



**Genzyme Corporation**  
500 Kendall Street  
Cambridge, MA 02142  
Tel 617-252-7500

August 3, 2009

**RE: Revised Cerezyme® (imiglucerase for injection) Supply Management plan effective August 3, 2009**

Dear Doctor:

As we previously informed you, we are in a period of temporary shortage of Cerezyme while we interrupt production to remediate a viral contamination of our manufacturing facility in Allston, Massachusetts. Throughout this period, our overarching objective has been to protect the most vulnerable Gaucher patients.

On June 22, Genzyme convened a Cerezyme Stakeholders Working Group (including physicians and patient advocacy leaders) to develop a set of recommendations (a "Guidance") for patient management designed to conserve supply for the most vulnerable patients. Across the U.S., physicians have begun to implement these recommendations. However, due to the complexities and time required to make these changes, we have not yet seen an adequate reduction in the usage of Cerezyme.

The projected levels of Cerezyme inventory are at a point where there is a high risk of not maintaining supply sufficient to protect the most vulnerable patients in August. The Cerezyme Stakeholders Working Group and FDA have been updated regarding this situation. As a result we have decided to begin more actively managing Cerezyme supply in order to preserve supply for the most vulnerable patients.

**As of Monday August 3, 2009**, Genzyme will implement a revised supply management plan which has been reviewed by the CSWG and which continues to have as its main objective conservation of Cerezyme supply for the most vulnerable patients.

The most vulnerable Gaucher patients will be defined as: **infants, children and adolescents (≤18 years old) and patients with type 2 or 3 Gaucher disease**. These patients should continue receiving Cerezyme according to their current dose and frequency, without any interruptions, and shipments will continue to these patients.

In addition, Genzyme will implement a **Cerezyme Emergency Access Program (CEAP)** which is designed to enable physicians to request Cerezyme for a limited number of other **adult patients with life-threatening clinical situations** defined as one or more of the following:

- Platelet count  $\leq 20,000/\mu\text{L}$  and/or documented bleeding diathesis
- Impending emergency non-elective surgery (e.g., splenectomy)
- Documented history of rapid and life-threatening disease progression following dose-reduction or treatment interruption.
- Other life-threatening clinical situation which requires Cerezyme

The number of qualifying patients who will be able to receive Cerezyme through CEAP will depend on inventory levels. The CEAP form with instructions regarding the process is enclosed.

Other adult patients (>18 years old) will not receive shipments of Cerezyme as of August 3<sup>rd</sup>, in order to conserve supply for the most vulnerable patients defined above.



**This revised supply management plan will be in effect through the month of August. At that point, the situation will be reassessed in consultation with the Cerezyme Stakeholders Working Group and the FDA, and we will inform the Gaucher community about any changes to the plan.**

We anticipate having additional information to share with the community at that time regarding the availability of additional inventory of Cerezyme that is not currently approved for finishing and release by FDA. In addition, Genzyme has submitted a treatment IND for our investigational oral small molecule to treat Gaucher disease, GENZ-112638, and we anticipate a response from FDA regarding that treatment protocol by the end of August. In the meantime, if you need any further information, please contact Genzyme Medical Information ([medinfo@genzyme.com](mailto:medinfo@genzyme.com) or 800-745-4447, option 2). A copy of the Cerezyme US Prescribing Information is included with this letter.

We acknowledge that this has been a challenging period for the entire Gaucher community. As of today, the sanitization of the Allston facility has been completed, and the process of restarting production of Cerezyme has already begun. Throughout this time, thank you for working together with us to protect the most vulnerable patients until the supply of Cerezyme is fully restored.

Sincerely,

A handwritten signature in black ink, appearing to read "John Yee".

John Yee, MD, MPH  
VP, Global Medical Affairs  
Genzyme Corporation

**Fabrazyme® (agalsidase beta) Update:** Initial adoption of the Fabry Stakeholders Working Group Guidance appears to be strong, with many indications that physicians and patients have chosen to alter their treatment plans by missing a dose, reducing their dose, or changing the frequency of infusions. At this time, there is not a need to revise this Guidance. However, during this period of supply constraint, there continues to be a need for physicians to make the appropriate clinical decisions for each Fabry patient in consideration of the Fabry Stakeholders Working Group Guidance until the Fabrazyme supply is fully restored.